REMARKS

Claims 1-32 and 35-40 are pending. Support for new claim 40 is provided by original claims 1 and 5.

I. Election/Restriction

Claims 28-30, 36 and 37 are withdrawn from consideration and the restriction requirement has been made final. Applicants are appreciative of the rejoinder of all of the claims excluding method claims 28-30 and blister pack claims 36-37. Process claims 28-30 have been amended to be dependent on the dosage form of claim 2 or 3. Therefore, it is requested that the amended process claims 28-30 be rejoined and examined together with the claims on which they depend.

Furthermore, blister pack claims 36-37, which continue to be withdrawn from consideration, recite the same active ingredients recited by claim 1, i.e., a H^+, K^+-ATPase inhibitor and a gastric antisecretory prostaglandin analogue. A thorough prior art search with respect to claim 1 would, by definition, involve the same filed of search and touch upon the merits of blister pack claims 36-37 which are expressly defined by the same patentably distinguishing features as claim 1. As such, the claims share the same special technical feature. Therefore, even though claims 36-37 may be classified differently, it would be an injudicious use of Patent Office resources and an unfair financial burden on Applicants if blister packs claims 36-37 continue to be withdrawn from the subject application.

Accordingly, Applicants request that amended claims 28-30 be rejoined and examined together with the claims on which they depend. Moreover, in the name of administrative efficiency and equity, withdrawal of the restriction requirement and rejoinder of blister pack claims 36-37 is requested.

II. Specification

The Examiner alleges that essential material required to practice the claimed invention is improperly incorporated in the specification by reference to non-U.S. applications or patents. Applicants respectfully disagree. It is clear from an inspection of the application that the disclosure of any non-U.S. applications or patents in the specification is directed to the background of the invention and/or illustrates the state of the art (See pp. 2-3). A fully enabling disclosure of the claimed invention is adequately provided by the remainder of the specification, including the Examples, without any reference to incorporated material.

For the foregoing reasons, the requirement to amend the specification is improper and withdrawal thereof is requested.

III. Claim Objections

Claims 7 and 8 are objected to under 37 C.F.R. §1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. This objection appears to be incorrect since neither claim 7 nor claim 8 depends, either directly or indirectly, on another multiple dependent claim.

Withdrawal of the claim objection is requested.

IV. Claim Rejections – 35 U.S.C. §112

Claims 1-27, 31, 32, 38 and 39 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Specifically, claim 1 is alleged to be indefinite in the use of the phrase "fixed unit dosage form". The phrase has been deleted from amended claim 1. Claims 19-21 are rejected in the use

of the phrase "at least one part of the tablet". Claim 19 has been amended by the deletion of the word "one". Claim 38 has been amended in the manner suggested by the Examiner.

Applicants submit that no new matter has been introduced by any of the claim amendments. In view of the foregoing, therefore, withdrawal of the §112 rejection is requested.

V. Claim Rejections – 35 U.S.C. §102

Claim 1 is rejected under 35 U.S.C. §102(b) in view of Tari, A. et al., "Digestive Diseases and Sciences", Vol. 42 ("Tari"). The Examiner alleges that Tari teaches a combination of omeprazole and enprostil for the treatment of peptic ulcer (page 1744).

Tari discloses the concomitant and separate administration of omeprazole and enprostil. In contrast, the claimed invention is directed to a *dosage form* containing a H^+, K^+-ATPase inhibitor and a gastric antisecretory prostaglandin analogue compound. Tari does not disclose a single dosage form containing both active ingredients. At page 7 of the Office Action, the Examiner states that Tari is "silent as to the oral dosage form". Therefore, even the Examiner has acknowledged the failure of Tari to disclose each and every feature of the claimed invention.

As such, Tari fails to anticipate the claimed invention. Withdrawal of the §102 rejection is requested.

VI. Claim Rejections – 35 U.S.C. §103

Claims 1-4, 11-27, 35, 38 and 39 are rejected under 35 U.S.C. §103(a) for alleged obviousness in view of US 6,365,184 to Depui et al. ("Depui") in combination with US 6,387,410 to Woolfe et al. ("Woolfe"). Depui discloses and claims a combination therapy including a proton pump inhibitor and a NSAID. Wolfe discloses a mixture of a NSAID and a prostaglandin to treat any side-effects associated with the administration of the NSAID. The

Examiner alleges that it would have been obvious, at the time the claimed invention was made, to combine Depui with Woolfe to arrive at the claimed invention comprising a proton inhibitor and a prostaglandin.

Claim 1 has been amended by the deletion of the open-ended "comprising" language. Amended claim 1 now recites the transition expression "consisting essentially of". By definition, the phrase "consisting essentially of" excludes additional unspecified ingredients which would affect the basic and novel characteristics of the invention defined in the balance of the claim. Thus, the patentable feature of claim 1 is the combination of an ATP-ase inhibitor and prostaglandin in a single dosage form. Claim 5 recites a calcium channel blocking agent as an additional ingredient of the dosage form of claim 1. New claim 40 similarly contains the transition expression "consisting essentially of". However, the patentable feature of claim 40 is the combination of the ATP-ase inhibitor, prostaglandin and calcium channel blocking agent in a single dosage form. Therefore, the claimed invention as defined by amended claim 1 and new claim 40 excludes ingredients such as NSAIDs.

Applicants respectfully submit, therefore, that the combination of Depui and Woolfe does not suggest the claimed invention and, *a fortiori*, would not result in the claimed invention. Withdrawal of the §103 rejection is requested.

VII. Claim Rejections – 35 U.S.C. §103

Claims 1-4, 11-27, 35, 38 and 39 are rejected under 35 U.S.C. §103(a) for alleged obviousness in view of Tari in combination with Depui. The Examiner acknowledges that Tari does not disclose an oral dosage form of the combination omeprazole-enprostil. Accordingly, the Examiner relies on Depui for a disclosure of an oral dosage form comprising a proton pump inhibitor and a NSAID. For the reasons set forth in Section VI, above, the combination of Tari

and Depui does not suggest the claimed invention which excludes additional unspecified ingredients such as NSAIDs which are required by Depui.

Withdrawal of the §103 rejection is requested.

VIII. Claim Rejections – 35 U.S.C. §103

Claims 5-10, 31 and 32 are rejected under 35 U.S.C. §103(a) for alleged obviousness in view of Depui in view of Woolfe and US 5,582,837 to Shell. Shell is relied upon for its alleged disclosure of a dosage form containing a calcium channel blocker for the treatment of gastric diseases.

As noted by the Examiner, the expected result would be a single dosage form comprising a combination of a proton pump inhibitor, NSAID, calcium channel blocker and prostaglandin. However, the claimed invention as defined by the amended claim 1 excludes a NSAID. Therefore, the combination of Depui, Woolfe and Shell does not suggest the claimed invention.

The following documents were not relied upon by the Examiner but are considered pertinent to Applicant's disclosure: US 5,840,332 to Lerner et al; US 5,980,882 to Eichman; and US 6,183,779 to Ouali et al. Applicants respectfully submit that none of the documents teach or suggest the claimed invention.

Claims 1-32 and 37-Versions With Markings to Show Changes Made:

1. (Twice amended) An oral pharmaceutical dosage form consisting essentially of [comprising at least] a H^+, K^+-ATPase inhibitor, [and] a gastric antisecretory prostaglandin analogue compound, and optional [as active components, and optionally] pharmaceutically acceptable excipients [, wherein the dosage form is in the form of a fixed unit dosage form].

19. (Twice amended) The tableted dosage form according to claim 2, wherein at least [one] part of the tablet is in the form of an extended release formulation.

28. (Twice amended) A process for the manufacture of the [a fixed] dosage form according to claim 3 [comprising a H^+, K^+-ATPase inhibitor and one or more gastric antisecretory prostaglandin analogue(s) in a capsule], the process comprising the steps of:

(a) preparing the H^+, K^+-ATPase inhibitor in the form of enteric coating layered pellets,

(b) preparing the gastric antisecretory prostaglandin analogue in the form of pellets coating layered with an extended release film,

(c) mixing the H^+, K^+-ATPase inhibitor pellets with the gastric antisecretory prostaglandin analogue pellets, optionally with pharmaceutically acceptable excipients, and

(d) filling the mixture into capsules.

29. (Twice amended) A process for the manufacture of the [a fixed] dosage form according to claim 2 [comprising a H^+, K^+-ATPase inhibitor and one or more gastric antisecretory prostaglandin analogues in a multiple unit tableted dosage form], the process comprising the steps of:

(a) preparing the H^+, K^+-ATPase inhibitor in the form of enteric coating layered pellets,

(b) mixing the H^+, K^+-ATPase inhibitor with pellets comprising the gastric antisecretory prostaglandin analogue, and optionally with pharmaceutically acceptable tablets excipients, and

(c) compressing the mixture into multiple unit tableted dosage forms [tablets] without causing any significant change of the acid resistance of the enteric coating layered pellets.

30. (Twice amended) The [A] process according to claim 29, wherein the pellets of the gastric antisecretory prostaglandin analogue are coating layered with an extended release layer [for the manufacture of a fixed dosage form comprising a H^+, K^+-ATPase inhibitor and one or more gastric antisecretory prostaglandin analogues in a multiple unit tableted dosage form, the process comprising the steps of:

(a) preparing the H^+, K^+-ATPase inhibitor in the form of enteric coating layered pellets.

(b) preparing the gastric antisecretory prostaglandin analogue in the form of coating layered pellets wherein the coating layer is an extended release layer,

(c) mixing the H^+, K^+-ATPase inhibitor pellets with the antisecretory prostaglandin analogue pellets and optionally with pharmaceutically acceptable tablet excipients, and

(d) compressing the mixture into tablets without causing any significant change of the acid resistance of the enteric coating layered pellets].

38. (Amended) The dosage form according to claim 4, wherein the dosage form further comprises a separating layer [is] applied under the enteric coating, wherein the separating layer separates the H^+, K^+-ATPase inhibitor from the enteric coating layer.

CONCLUSION

Applicants respectfully submit that the Amendment and Remarks are responsive tot he Office Action. Applicants request allowance of the claims.

Authorization is hereby given to charge any additional fee required in connection with the communication to Deposit Account No. 23-1703.

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Respectfully submitted,

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